510(k) Summary

DEC 13 2013

Submitter Information: Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda, Germany

Establishment Registration Number: 3006611221

Contact Person: Grant Geckeler
Free lance consultant
4375 Prado Road, Suite 103
Corona, CA 92880
Phone: +1 714 283 1683
Fax: +1 714 637 2460
E-mail: ggeckeler@geoinc.org

Name of Device:

Common Name: External CSF Drainage System
Proprietary Name: LiquoGuard CSF System
Consists of: LiquoGuard CSF System pump and LiquoGuard CSF System tube set

Classification: Shunt, Central Nervous System and Components, Class II, 21 CFR § 882.5550

Product Code: JXG

Device Description:

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the "gold standard" for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis. For CSF drainage, dripping chambers are still being used widely. In contrast, dripping chambers for IV infusion have been mostly replaced by perfusors (syringe pumps).

The LiquoGuard CSF System consists of a pump and a corresponding tube set with pressure sensors. The dynamic range of this system is from -15mmHg to +75 mmHg. The tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via Luer-Lock and the LiquoGuard CSF System device via cable connector. The device then continuously measures the pressure inside the tube and operates a tube pump whenever the actual pressure is higher than a preselected target pressure. Thus the LiquoGuard CSF System combines CSF drainage and intracranial pressure (ICP) monitoring with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient mobility (by its battery back-up).

Intended Use:

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure using pressure sensors and a pump, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure up to 75 mmHg and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Substantial Equivalence:

The Möller Medical LiquoGuard CSF System is substantially equivalent to the CSF drainage systems listed below with regard to intended use, design, operating principles, and materials.

Integra NeuroSciences Corporation	K030289, K032817
Codman & Shurtleff, Inc.	K061568

The Möller Medical LiquoGuard CSF System shares features with, the intracranial pressure monitor listed below (the shared features include CSF pressure monitoring, semiconductor sensor principle, display, alarm functions and data recording).

Camino NeuroCare.™ Inc.	K962928

By using the LiquoGuard CSF System, in the same way as in existing systems, intrathecal pressure can be measured; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement.

Additional details for comparing these CSF Systems are contained in Table 8 and Table 9.

Table 8: System Comparison

Product / Component	Dipping chamber systems		ICP Monitor system	Combination
	Hermetic Plus External CSF Drainage System	CODMAN EDS 3 CSF	Multi-Parameter Monitor (MPM)	LiquoGuard CSF System
Tube set disposable	•	•		•
CSF drainage bag	•	•		•
Pressure transducer			•	•
Micro controller			•	•
Software operated			•	•
Data storage			•	•
Button / Foil keypad			•	•
Screen			•	•
Ports			•	•
Casing			•	•
Power supply			•	•

Table 9: Device Comparison

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Reference Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure and measurement of CSF pressure.	Externally draining of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients.	External draining of cerebrospinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and patient.	Measurement of intracranial pressure in the ventricles and during the cerebrospinal fluid (CSF) drainage.
CSF sterile tubing set with pressure sensor and drainage bag	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Dual transducers. **CSF Collection Bag:** 500ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** Single transducer. **CSF Collection Bag:** 700ml.	**Tubing material:** Polyvinyl chloride (PVC). **Pressure sensor:** None. **CSF Collection Bag:** 700ml.	**Tubing material:** Not applicable. **Pressure sensor:** Single transducer. **CSF Collection Bag:** Not applicable.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on differential pressure (Pascal's law of fluid statics) caused by height difference between patient and dripping chamber.	Based on pressure equivalence (Pascal's law of fluid statics) inside the head.
Height alignment of patient and	Device can be positioned arbitrarily, only the pressure	Alignment is critical because it controls the	Alignment is critical because it controls the	Device can be positioned arbitrarily; the pressure sensors need to be

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Reference Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
device	sensor needs to be aligned.	target pressure.	target pressure.	incorporated.
Device adjusting fluid flow	LiquoGuard CSF System peristaltic pump controlled by pressure at sensor location.	None - fluid flow is not controlled or limited.	None - fluid flow is not controlled or limited.	No drainage.
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF System.	Pressure is sensed and may be recorded by external device. Drained volume is unmonitored.	No monitoring functions.	Pressure, pressure curve and temperature are monitored and recorded.
Alarm functions enhancing patient safety	Many alarm functions integrated in the system: * Pressure too high. * Pressure too low. * Physiological pressure pulsation lost. * Pressure remains constant for too long. * Dual sensors deviate in readings (defective sensor). * Watchdog or main controller does not respond to each other's requests (device or software malfunction). * Battery low.	No integrated alarm functions.	No alarm functions.	Few integrated alarm functions: * Pressure too high. * Battery low.

	Möller Medical LiquoGuard CSF System	Primary Predicate Devices		Reference Device
		Integra LifeSciences Corporation (K030289, K032817)	Codman & Shrutleff, Inc. (K061568)	Camino NeuroCare,™ Inc. (K962928)
Measured pressure range	-15mmHg to +75mmHg.	No measurement.	No measurement.	-10mmHg to +250mmHg.
Physical dimensions	315mm x 210 mm x 280 mm (H x W x D). 4.8 kg.	-	-	274 mm x 216 mm x 89 mm (H x W x D). 4.3 kg.
Displayed parameters	Actual ICP value, ICP waveform, ICP trend. Display resolution of 1 mmHg.	No display.	No display.	Actual ICP value, ICP waveform, ICP trend, intracranial temperature, Cerebral Perfusion Pressure. Display resolution of 1 mmHg.
Sensor type	Dual transducer.	Single transducer.	No sensor.	Fiber-optic single pressure transducer.
Scheduled preventive maintenance	Every 12 months	No	No	Every 18 months
Battery	Rechargeable sealed lead acid. Charge time: 8h. Operation time: 3h.	No battery.	No battery.	Rechargeable sealed lead acid. Charge time: 8-10h. Operation time: 1-2h.

Summary of substantial equivalence discussion

Many if not all risks leading to accidental, cerebral herniation in both systems (traditional drainage and ICP monitors) can be reduced or even eliminated by the LiquoGuard CSF System.

The LiquoGuard CSF System is working equivalently to a drip chamber, with the additional safety that, using LiquoGuard CSF System, a partial or intermittent catheter occlusion may be detected in many cases: In difference to the dripping chamber which must be an open system during drainage the LiquoGuard CSF System can measure the hydrostatic pressure inside the tube (drainage system) during drainage because the drainage system is closed, combined with a CSF pressure monitor and its features like displaying pressure values, curves and trends and enabling alarm functionality. The principles of measurement are comparable to the ICP monitor and its pressure transducer as both systems measure the pressure of the surrounding liquid. The only difference is the position of the transducers, and the fact that LiquoGuard uses dual transducers for redundancy.

The LiquoGuard CSF System behaves comparable to a traditional drainage system even in the case of a clotted catheter or collapsed ventricles. It is able to sound and display alarms to operators, is portable, can be used while not connected to the mains, records and stores data and can be connected to bedside monitor systems, same as the Multi Parameter Monitor.

By combining the functionality of dripping chambers with the features of a computer operated device (ICP monitor) and adding a peristaltic pump the LiquoGuard CSF System benefit is potentiated as some major problems are solved (elimination of sensor drift problematic, protection of accidental over and / or under drainage, pressure measurement simultaneously with CSF drainage, etc.).

Summary and Conclusion of the Performance Testing:

The LiquoGuard CSF System has the same indication for use as the predicate devices (measurement and drainage of CSF). In addition, the LiquoGuard CSF System tubing set is made from the same materials as the predicate devices, and because the risks associated with the surgical insertion of a CSF drain are not dependent on the CSF drainage system chosen, no new safety or effectiveness concerns are introduced over the predicate devices. Please refer to Table 10 for the list of bench tests – there you find a list of all bench tests that have been performed.

The test series exhibits a very wide range of performance tests and all necessary and required tests for the LiquoGuard were appropriate performed and all tests passed according to the predetermined pass/fail criteria. Particularly highlighting are tests which serve to check the pressure and alarm systems. For this purpose, a plurality of measurements has been carried out to verify the critical components.

Table 10: List of bench test

Pressure measurement	✓ Absence of sensor drift during packaging / sterilization ✓ Absence of sensor drift during ageing ✓ Precision of displayed pressure at various pump rates and pressure loads
Pressure regulation	✓ Endurance test with in-vitro simulated patient ✓ Performance comparison with drip chamber ✓ Reliability of pump shut-off with negative pressures ✓ Device functions independent of positioning
Volume and flow measurement	✓ Precision of total volume and flow (pump rate) measurement
Alarm functions related to patient condition	✓ Pressure alarms ✓ Pulsation alarm (indication for events like: catheter occlusion collapsed ventricles and disconnected catheter) ✓ Pressure too constant (indication for events like: catheter occlusion collapsed ventricles and disconnected catheter) ✓ Influence of pressure on catheter walls ✓ Detection of clogged catheter
Alarm functions related to device functions	✓ Defective/disconnected sensors ✓ Disconnected/leaking tube set ✓ Battery low ✓ Main controller/watchdog cross-check ✓ Double safety ✓ Tube set too old ✓ Battery defective
Mechanical handling and operation	✓ Disposable check for single-use ✓ Wrong tube set insertion ✓ Opening of front panel ✓ Disposable check for age
Endurance	✓ Automatic switch to battery upon power failure ✓ Tube set durability
Other	✓ External connectivity

Summary and Conclusion of the Clinical Study:

Drawing on the user base and combining similar, independent studies from several hospitals into one data basis, we collected 413 patient records on treatments using the LiquoGuard (LG) as well as the predicate devices (drip chambers). We identified a number of "adverse events" and compared their rate of incidence for both cases (LG vs. predicate) for the total patient population as well as certain patient categories, e.g. medical indication.

Since the two CSF drainage methods (LiquoGuard and drip chamber) apply the same therapy (drainage) to the patients, we expected to obtain similar results. Indeed, the data show a great similarity. E.g., total rates of incidence of adverse events are for each type of event very close, with most small variations in favor of the LiquoGuard.

The findings support the equivalence of LiquoGuard and the listed predicate devices.

JXG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 13, 2013

Möller Medical GmbH
c/o Mr. Grant Geckeler
1612 Jenks Drive
Corona, CA 92880

Re: K121248
Trade/Device Name: LiquoGuard CSF System
Regulation Number: 21 CFR 882.5550
Regulation Name: Shunt, Central Nervous System and Components
Regulatory Class: Class II
Product Code: JXG
Dated: May 13, 2013
Received: September 16, 2013

Dear Mr. Geckeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: **K121248**

Device Name: **LiquoGuard CSF System**

Indications for Use:

The LiquoGuard CSF system is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure. The LiquoGuard CSF system controls CSF pressure using pressure sensors and a pump, thus taking the role of the conventional CSF dripping chamber and collection bag (predicate devices). The LiquoGuard CSF system also monitors intracranial pressure up to 75 mmHg and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions not offered by the passive dripping chamber systems.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S